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112701-703

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EXAMINER

GWARTNEY, ELIZABETH A

ART UNIT

PAPER NUMBER

1794

NOTIFICATION DATE

DELIVERY MODE

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ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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chicago.patents@klgates.com

ATTACHMENT TO ADVISORY ACTION

Applicants' amendment to the claims filed on 05/15/2009 has been fully considered but is denied entry for the following reasons:

The amendment raises new issues that would require further search given that such limitations were never previously presented in the claims or as part of the independent claims.

Given the amendment filed on 05/15/2009 is denied entry, the arguments explicitly pertaining to the amendment are not addressed.

Regarding protein content, Applicants submit that *Spivey-Krobath* and *Brassart* both fail to disclose or suggest a nutritional composition comprising about 4.5 to about 6 g protein/100 ml composition.

Given that the present claims require about 4.5 to about 6 g protein/100 ml, since "about 4.5 to about 6.5 g protein/100 ml" allows for concentrations slightly above 6 g and slightly below 4.5, it is clear that the ranges disclosed by *Spivey-Krobath*, i.e. 7 g protein/100ml, and *Brassart*, i.e. 3.8 g protein/100ml, overlap with those presently claimed.

In the alternative, it is apparent that the instantly claimed amount of protein and that taught by *Spivey-Krobath* and *Brassart* are so close to each other that the fact pattern is similar to the one in *In re Woodruff*, 919 F.2d 1575, USPQ2d 1934 (Fed. Cir. 1990) or *Titanium Metals Corp. of America v. Banner*, 778 F.2d 775, 227 USPQ 773 (Fed.Cir. 1985) where despite a "slight" difference in the ranges the court held that such a difference did not "render the claims patentable" or, alternatively, that "a prima facie case of obviousness exists where the claimed ranges and prior art ranges do not overlap but are close enough so that one skilled in the art

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would have expected them to have the same properties”(see MPEP 2144.05 – I. Overlap of Ranges)

Regarding inherency, Applicants argue that because *Spivey-Krobath* and *Brassart* both fail to disclose the presently claimed compositions having certain protein amount, it is improper to allege that the compositions of *Spivey-Krobath* and *Brassart* have viscosity ranges that are identical to the viscosities of the presently claimed compositions. Applicants argue that Examiner has fails to show that the compositions of *Spivey-Krobath* and *Brassart* "necessarily" provide for compositions having a viscosity of about 30-80 mPas.

Given that *Spivey-Krobath* and *Brassart* both disclose protein in amounts that overlap or would be expected to have the same properties as the amounts presently claimed, it is clear that the references as combined disclose compositions identical to that presently claimed. Thus, given that *Spivey-Krobath* and *Brassart* disclose compositions identical to that presently claimed, it is clear that the compositions would inherently possess a viscosity of about 30-80 mPas.

Applicants submit that *Spivey-Krobath* and *Brassart* fail to mention the unexpected benefits of improved intestinal transit, gut flora and gut comfort provided by the use of acacia gum in the presently claimed invention.

Because there is substantial evidence to support determination of a prima facie case of obviousness over each of the applied prior art references, the burden of proof was properly shifted to the applicants to rebut the prima facie case by presenting persuasive arguments or evidence (e.g. unexpected results). *In re Mayne*, 104 F.3d 1339, 1343, 41 USPQ2d 1451, 1455 (Fed. Cir. 1997). ("With a factual foundation for its prima facie case of obviousness shown, the

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burden shifts to applicants to demonstrate that their claimed fusion proteins possess an unexpected property over the prior art.")

Unexpected results must be established by factual evidence; mere argument or conclusory statements in the specification do not suffice. *In re Geisler*, 116 F.3d 1465, 1470, 43 USPQ2d 1362, 1365 (Fed. Cir. 1977) (quoting *In re De Blauwe*, 736 F.2d 699, 705, 222 USPQ 191, 196 (Fed. Cir. 1984)). Unexpected results must be established by comparing the claimed invention against the closest prior art. *In re De Blauwe*, 736 F.2d 699, 705, 222 USPQ 191, 196 (Fed. Cir. 1984) ("[A]n applicant relying on comparative tests to rebut a prima facie case of obviousness must compare his claimed invention to the closest prior art."); accord *In re Merchant*, 575 F.2d 865, 869, 197 USPQ 785, 788 (CCPA 1978).

In this case, Applicants have not provided any evidence to show that the nutritional composition of modified Spivey-Krobath et al. or of modified Brassart et al. would not exhibit the same benefits as the presently claimed invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Gwartney whose telephone number is (571) 270-3874. The examiner can normally be reached on Monday - Thursday; 7:30AM - 5:00PM EST, working alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Keith Hendricks can be reached on (571) 272-1401. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/E. G./

Examiner, Art Unit 1794

/KEITH D. HENDRICKS/

Supervisory Patent Examiner, Art Unit 1794